

**COMPUTED TOMOGRAPHY FINDINGS IN PATIENTS WITH
MINOR HEAD TRAUMA PRESENTING WITH A HISTORY OF
LOSS OF CONSCIOUSNESS AND/OR AMNESIA, GLASGOW
COMA SCALE 15 AND NO FOCAL NEUROLOGICAL DEFICIT**



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DECLARATION

I, Chuma Singata hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Signed

Date: 14/08/2017

I dedicate my research to the Sovereign God for giving me grace, wisdom and intellect to get this far in my career journey.

To my parents, AD Singata and NT Singata, for all the sacrifices, love and unwavering support.

To my friends who played a big role in making this a reality.

To the Groote Schuur radiology department consultants and Professor Beningfield for guidance and teaching.

Publications and presentations

This work has never been published or presented at a congress.

Abstract:

Background:

South Africa is a developing country with limited resources. Currently, in our institution, patients who have suffered a minor head injury with a Glasgow Coma Scale (GCS) 15, loss of consciousness (LOC) and amnesia obtain a computed tomography (CT) scan, regardless of the cost that is incurred by the use of this limited resource. Applying recommendations in developing countries requires consideration of resource limitations and patient burden.

Objective:

Our objectives were twofold:

1. To determine the number of abnormalities found on routine head CTs in patients who have a history of LOC and amnesia/PTA post trauma, but with a normal mental status (GCS 15) on presentation to the trauma unit.
2. To determine the clinical value of routine CT scan of the head in patients who have suffered minor head injury with GCS 15, LOC and amnesia.

Methods:

The CT scan reports of 460 patients with minor head injury, GCS 15, LOC and amnesia were reviewed retrospectively in the radiology unit of Groote Schuur Hospital between the years 2012 and 2014. These patients were assessed by the trauma doctor and referred to the radiology department for a CT scan of the head. Reports had been prepared and verified by a radiology specialist or senior registrar.

Results:

The findings on CT were categorized as significant and insignificant. A total of 33 patient reports (7%) met the criteria of significant findings that required neurosurgical intervention. (CI 4, 7-9, 6). 320 patients (70%) had normal findings while 107 patients (23%) had insignificant findings.

Conclusion:

CT scan of the head in minor head injury patients with normal mental status (GCS 15) is recommended even in the face of the limited resource in view of our study results.

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1. Introduction

Based on CT request forms received in our radiology department, it appears that the current trend in our institution requires trauma patients with history of loss of consciousness (LOC) and post traumatic amnesia (PTA) to undergo a computed tomography (CT) scan of the head even when they present with a normal mental status (Glasgow coma scale (GCS)15/15). South Africa is a developing country with resource limitations and CT scanning is an expensive radiological investigation available only in large referral and regional centers. It is important to evaluate our management protocols to utilize resources optimally and to make them relevant nationwide. This study focuses on determining whether CT scanning of trauma patients with a history of LOC or PTA but who have a GCS of 15/15 and no focal neurology on presentation yields pathology that will change medical / surgical management. Before 1995, the terms “mild head injury” and “minor head injury” were used interchangeably.¹

The literature provides multiple definitions of mild/minor head injury, complicating assessment of clinical presentation, imaging, outcome and decision making regarding patient management.^{1, 2}

Mild head injury was first defined as “less severe” traumatic head injury (THI) accompanied by rapid healing.³ More recently, mild head injury has been defined as head injury that results in loss of consciousness (LOC) for up to 30 minutes and amnesia/post traumatic amnesia (PTA) in patients presenting with a GCS of 13-15.^{4, 5} A larger proportion of mild head injury patients present with a GCS of 15, compared with those who present with a GCS of 13 or 14. Several authors have argued that combining in one group all patients with a GCS of 13 to 15 underestimates the true severity of the injury in those patients with scores of 13 or 14.^{6, 8, 9, 10, 11.}

The implication of this being that those presenting with a GCS of 15 should be considered in a separate category, referred to as minor head injury.⁸

In an attempt to address the need for CT scan in minor head trauma, this study aimed to correlate the CT head findings in a group of patients presenting to the Groote Schuur trauma unit with a history of acute head injury but a GCS of 15 at the time of scanning.

2. Literature review

2.1 Epidemiology

There has been an increase in the national burden of MHI and the incidence is higher than that reported.¹² Accuracy in describing epidemiology of traumatic brain injury (TBI) has been made extremely difficult by variable definitions and classification of TBI over the years, along with discrepancies in data collection.¹³ According to the Centers for Disease Control and Prevention, approximately 1.7 million Americans sustain traumatic brain injury (TBI) every year. Of those patients, 75–90% are classified as mild,¹⁸ making mild TBI a more common cause for presentation to the emergency room than stroke.¹⁴

South African statistics are poorly reported. Nel *et al.* (1991), conducted a study of the epidemiology of traumatic head injury in Johannesburg (South Africa), in which the total annual incidence of TBI was found to be 316 per 100,000 population.¹⁵

2.2 Risk factors in mild head injury

Referrals to the radiology department at GSH include community assault, pedestrian and motor vehicle accidents, falling from a height, gunshot injury and occupation related trauma often in association with alcohol intoxication. Many trauma head scans are entirely normal. Risk factors that have been identified as having a strong association with scan abnormality are advanced age, skull fracture, loss of consciousness, amnesia, vomiting and headaches.¹⁶

2.2.1 Age

Patients older than the age of 60 years are more prone to sustaining significant head injury than those who are younger.^{11, 16, 17} In a study of patients over the age of 60 years with MHI, Mack *et al.*¹⁹ found a 14% incidence of intracranial injury (ICI) diagnosed on CT, which they attributed to increased syncope and tendency to falls. The gross brain weight decreases by 200 grams from the age of 50 to 80 years, resulting in a significant increase in the extra-axial space.¹⁹ This predisposes the elderly to tearing of the bridging vessels during relatively minor trauma.

Intracranial hematoma may accumulate without immediate rise in intracranial pressure, hence the delayed presentation with chronic subdural hematoma.¹⁹

2.2.2 Skull fracture

Skull fracture has a strong association with intracranial injury.^{17, 24, 10} Servadie *et al.* states that 80% of patients with skull fracture develop significant intracranial injury.¹⁷ The World Federation of Neurosurgical Societies (WFNS) Neuro-traumatology Committee regards patients with a GCS of 14 or 15 plus a skull fracture and/or neurological deficit as high risk MHI classification. Therefore they recommend a plain skull radiograph to be done in district hospitals where there is a scarcity of health resources, in order to triage such patients.¹⁶

Gomez *et al.* analyzed factors which were associated with abnormal CT in patients with GCS 13-15. In this study, 38% of MHI patients with fracture had abnormal CT findings compared to those without fracture. Only 0.3% of patients with a GCS of 15 and no skull fracture, had abnormal CT findings. These authors concluded that there is a very low incidence of positive CT findings in patients with a GCS of 15 that would require neurosurgical management.¹¹

2.2.3 Loss of consciousness, vomiting and headache.

Amnesia for the traumatic event and PTA are defined as a state of being unable to remember the traumatic event and following events respectively.^{6,7} Miller *et al.* (1995), defined LOC as a witness viewing the patient in a state of unconsciousness and reporting this fact to the attending clinician in charge of the patient's care.⁶

The period of amnesia and occurrence of a transient LOC has been taken as an essential condition to differentiate a brain injury from a scalp bruise or a skull injury.¹⁷ LOC indicates significant concussion.¹⁰ Smits *et al.* (2007) proposed that a history of PTA/ LOC should be observed as one of the risk factors for neuro-cranial complications and not as condition that is indispensable for MHI.⁷ The occurrence and duration of LOC can be difficult to quantify in practice, as a reliable observer is not always available.¹⁷ Hsiang *et al.* (1997), found that a significant number of patients were not able to confirm the presence and duration of history of loss of consciousness. In addition, patients could not distinguish post-traumatic amnesia from impaired consciousness.¹⁰ Therefore, the reliability and significance of history of consciousness

still remains unclear. When vomiting after head injury was studied as a specific clinical sign, it was not shown to be related to CT scan abnormality. The authors also found that headache is a subjective and common complaint and is therefore an unreliable clinical sign in assessing severity of head injury.¹⁰

2.3 The Glasgow coma score (GCS)

In 1970, two parallel studies that were funded by the National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services, focused on comatose patients with severe head injuries and the prognosis of medical coma. The difficulty in these studies was defining severe head injury.^{37,39}

In the United Kingdom, Teasdale and Jennet initially developed a ‘coma index’ for research purposes to study the level of consciousness in patients with severe head trauma and to measure objective function in comatose patients. This later evolved into a coma scale which was famously published in 1974. Named after the town in which the authors worked, the Glasgow Coma Scale improved common language of communication in reporting neurological findings observed at the bedside amongst clinicians and health workers.^{38,39}

The GCS is now widely used internationally³⁹ and is now a generally acknowledged scale to accurately quantify the severity of traumatic brain injury.² Classification of patients with MHI has fundamentally depended upon the GCS. GCS defines the severity of a TBI within 48 hours of head injury as illustrated in Appendix 2A.¹³ Limitations of the GCS include failure to consider head injury symptoms such as headache, nausea and vomiting, which may be important risk factors in predicting abnormal CT scan especially in patients with GCS 15 and LOC/PTA.²² Therefore, GCS alone may be insensitive in defining this heterogeneous subgroup of patients.⁴

In a prospective study looking at patients with GCS 15, LOC and amnesia, Miller *et al.* (1996) concluded that routine CT in patients presenting with only PTA or history of LOC is not indicated since only 3% of the patients in their study had minor abnormalities. Two years later, these authors proposed clinical variables that may be used to triage minor head injury patients with GCS 15 and with or without LOC/PTA. These variables included one or more of the following symptoms and signs: depressed skull fracture, severe headache, vomiting, and nausea. The use of these variables was found to reduce the number of performed head CT scans by up to

61%.²⁴ Their criteria had 65% sensitivity and 63% specificity in detecting patients with an abnormal CT scan and 100% sensitivity for detecting patients who required surgical intervention.²⁴

In a prospective study of 1170 patients with GCS 15 and LOC/PTA, Nagy *et al.* (1999) showed the relationship between head injury symptoms and abnormal CT scan by comparing patients with normal scans with those with abnormal scans. The group of patients that had abnormal results was more likely to have nausea, vomiting, seizures, dizziness and headache. Based on this study, these authors suggested that every patient who suffers from a blunt head injury associated with LOC or PTA, and presents with GCS 15 must have CT scan examination of the brain because of the minimal but “real” risk of traumatic brain injury.^{23,26} Sarvadie *et al.* (2001) also classified a similar group of patients as medium risk with a relative higher risk of intracranial hematoma and advised that where there is a single CT machine available in an area of 100,000 people or less, a CT scan should be obtained for such patients.¹⁷

2.4 Diagnostic tools for minor head injury

CT scan of the brain is the gold standard to diagnose traumatic brain injury.⁴ It is the modality of choice in trauma centers, and helps with rapid and accurate diagnosis of head injury, from a simple skull fracture to severe brain injury.^{4,25, 26} The practice of defensive medicine is common and costly. Defensive medicine is the act of requesting tests, treatments and procedures with the main aim of protecting the doctor from liability rather than substantially furthering the patient’s diagnosis or treatment.²⁷ Fear of missing pathology is often cited in requesting head CT scan.²⁷ Currently in the US, 1 million patients with blunt head injury are scanned annually.²⁹ Different studies have reported a wide range (0.7% and 20%) of significant intracranial lesions on CT^{28,33,31}. Despite inconclusive epidemiological data, in the developed world the number of CT scans continued to rise trauma patients with a suspected traumatic intracranial injury.^{4,25,26}

Without specific guidelines, there is evidence that the burden of head CT for MHI will increase in future.¹⁶ Furthermore, the indications are often inconsistent and may result in inefficient use of resources, both in terms of equipment and personnel.³² Besides the continuing wasteful use

of the CT resource plus ever increasing CT demand, there are also associated risks of radiation exposure.²

2.5 Decision rules for CT scanning patients with mild head injury

Routine CT scans in patients with a GCS of 15 after MHI has been questioned.³⁰

With CT scanning being a costly modality in resource limited countries, sparing utilisation for patients with MHI could lead to a decrease in health care costs.¹⁶ Applying of the clinical variables to validate the use of CT brain scanning is appropriate to assist clinicians to triage patients that need urgent CT scanning with confidence.^{16, 24} In the rural setting, rational safe guidelines for the use of CT would be invaluable.

There is a diversity of decision rules that have been well researched to discern the MHI patients who would benefit from head CT scanning. Decision rules help clinicians to identify patients who are likely to have clinically significant lesions on CT. These are aimed at reducing costs incurred in performing unnecessary CT scans.⁴ These include New Orleans Criteria (NOC), Canadian Assessment of Tomography for Childhood Head injury (CATCH), Canadian CT Head Rule (CCHR), ‘Prediction of intracranial computed tomography – The CHIP Prediction rule’.^{4, 7, 31, 35} Recently, the Kimberly CT head rule was conceived in the Northern Cape province of South Africa where large distances and limited resources pose particular challenges.³⁷

These various criteria aim to recognise trauma patients who need neurosurgical management after a mild head injury with 100% sensitivity. However, the diversity of these rules highlights the difficulties that any researcher would encounter in MHI.² The Canadian CT Head Rule (CCHR) and the New Orleans Criteria (NOC) are the most rigorously researched and tested.^{2, 4}

The “CT in Head Injury Patients” (CHIP) (appendix 2B) was designed by Smits *et al.* (2007), who focused at developing a universally relevant and user friendly prediction rule for the selective use of CT in patients with MHI presenting to the emergency department and is not limited by the presence or absence of LOC. It was found to be efficient and accurate to triage patients with MHI.⁷

The “Prediction of intracranial computed tomography, findings in patients with minor head injury by using logistic regression” rule was developed by Saadat *et al.* (2009).⁴ The decision

rule enables physicians to triage patients with MHI who are most likely to have intracranial injury on CT scans. Its simplicity allows for use by doctors in resource limited countries. Nonetheless, the authors caution that the rule must be researched again on a more inclusive and bigger sample size.³⁵

The New Orleans criterion (Appendix 2C) was developed by Haydel *et al.* (2000). This criterion addresses the limitations of using the GCS alone to determine which patients of the MHI group should be referred to CT scanning.⁴ Application of the NOC is expected to yield 22% reduction in use of CT scan for minor head injury. It has a higher sensitivity for traumatic brain injury yet at the cost of specificity (100% and 12.7% respectively).^{2, 4}

Stiel *et al.* (2001) developed the CCHR (appendix 2D) after studying 3121 patients.³¹ Harnan *et al.* (2005) argue that the CCHR has the most constant and satisfactory sensitivity to recognize injuries that require neurosurgical management, with reasonable specificity to enable justifiable use of head CT.^{31,32} This rule is by far the most recognized with the most reasonable outcomes. The CCHR high and medium-risk criteria have sensitivity varying from 99% to 100% and specificity from 37% to 48% for injuries that require neurosurgical management. The higher specificity and reliability give it a greater potential impact on CT ordering rates than the NOC.
2,32

The Kimberley Hospital rule (appendix 2E) was proposed in 2012 specifically for use in the South African setting. It is an easily applicable guideline in a busy emergency unit. Bezuidenhout *et al.* (2013), after comparing the best validated and most used head decision rules internationally (such as the National Institute of Health and Care Excellence (NICE) and the ‘Prediction of intracranial computed tomography – The CHIP Prediction rule’), found that the use of the KHR to patients with traumatic brain injury achieved 95% sensitivity and 45 % specificity, thus theoretically making it comprehensively applicable in developed and in underdeveloped communities. The KHR allows patients with GCS 15 and LOC to be imaged semi urgently in 8 hours. This alleviates the cost of urgent transportation of patients, as some of these patients may require airlifting. The leeway of 8 hours allows for use of road transport.

Of note, this rule triages head injury patients according to severity and urgency. In doing so, the timing of emergency CT brains is justified without reducing the number of scans performed, thereby decreasing the demand to the limited resource. ³⁴

3. Study aim and objectives

I. Determination of the number of abnormalities found on routine head CT in patients who have a history of LOC, amnesia/PTA post trauma, but with a normal mental status (GCS 15) on presentation to the trauma unit.

II. Determination of the clinical value of routine CT Head by calculating the percentage of patients with acute minor head injury referred for CT with a GCS 15/15 and history of LOC/amnesia, but who are found to have a significant head injury requiring neuro-surgical management.

4. Methods

4.1 Methods, materials, inclusion and exclusion criteria

This is a retrospective descriptive study conducted at Groote Schuur Hospital, Cape Town, a level 4 referral hospital.

The data was collected retrospectively by an authorized personnel, as approved by the Human Research Ethics Committee of the University of Cape Town (HREC REF: 098/2015).

Philips picture archiving and communication system (PACS) was used to acquire request forms and patients reports between 2012 -2014. To meet the study criteria, all patients with a documented normal mental status (GCS 15/15), a history of LOC or amnesia were included. This group of patients was isolated, saved in a separate folder and used for the purpose of this study.

Children who were less than 13 years old, adults with illegible requests or reports, inadequate CT scans (e.g. with movement artifact, in the incorrect window), non-finalised reports (i.e. not reviewed by a senior radiologist), penetrating trauma, clinically palpable or radiographically detected (skull x-ray) skull fracture, seizure and/or focal neurology (e.g. hemiparesis, cranial nerve signs) were excluded. Patients were not excluded for drug, alcohol, multisystem trauma or use of anticoagulants as long as their GCS was 15

Only the final report of either a senior registrar (>2 years of neuroradiology training) or a qualified radiology consultant was used for the purpose of the study. Patients were allocated consecutive numbers for the purpose of data capture and statistical analysis as well as confidentiality.

CT head scans were performed at GSH on one of two helical scanners – a 6 slice Siemens machine and a 120 slice Toshiba machine with both bone, brain and epidural windows obtained for all patients.

4.2 Sample size calculation,

Sample size was calculated using the equation for estimating a single proportion from a large sample:

$$n = \frac{P(1 - P)Z_{1-\alpha}^2}{d^2}$$

n: Sample size

P: Anticipated population proportion

Z = 1.96, Assuming 95% confidence interval

d: Required precision on either side of the confidence interval

This equation assumes random sampling takes place.

Using an acceptable precision of 1.5%, n=497

4.3 Data collection

Data were collected by the primary investigator using a standardised collection sheet (appendix 3). Categorical data—age, sex, LOC, amnesia/PTA to event, signs of head trauma: ecchymosis, abrasion, swelling and symptoms: nausea, vomiting, headache, dizziness—were collected for all the patients within the clinical referral category. CT scans were considered abnormal when a subdural, epidural or subarachnoid haematoma was noted and when parenchymal contusions, cerebral edema, hydrocephalus, cerebral herniation (midline shift, uncal or transtentorial), pneumocranium and skull fracture were reported as present.

Patients with positive CT findings were categorised into significant and non-significant CT findings according to their most severe finding. Significant abnormalities included subdural and extradural hematoma, contusion, cerebral edema, cerebral herniation, hydrocephalus and depressed/base of skull fractures (not detected clinically or on prior skull radiograph, which would have necessitated exclusion). Non-significant findings include ecchymosis, scalp swelling and linear skull fracture.

4.4 Statistical Analysis

Data were presented as frequencies and percentages and analysed with the χ^2 and t tests. Confidence interval was calculated to determine the significance of the results.

5 Results

5.1 Overall distribution of CT scan findings in all patients.

The CT scans of 460 patients were reviewed during the study period.

All patients had a history of head trauma, LOC and/or amnesia with mental status (GCS of 15) as a major criteria. Exactly 320 scans (70%) were entirely normal whilst 140 scans (30%) had abnormal CT finding (Figure 2). Of these with abnormal findings, 33 patients had significant findings. The findings in 107 patients were non-significant. (Figure 3)

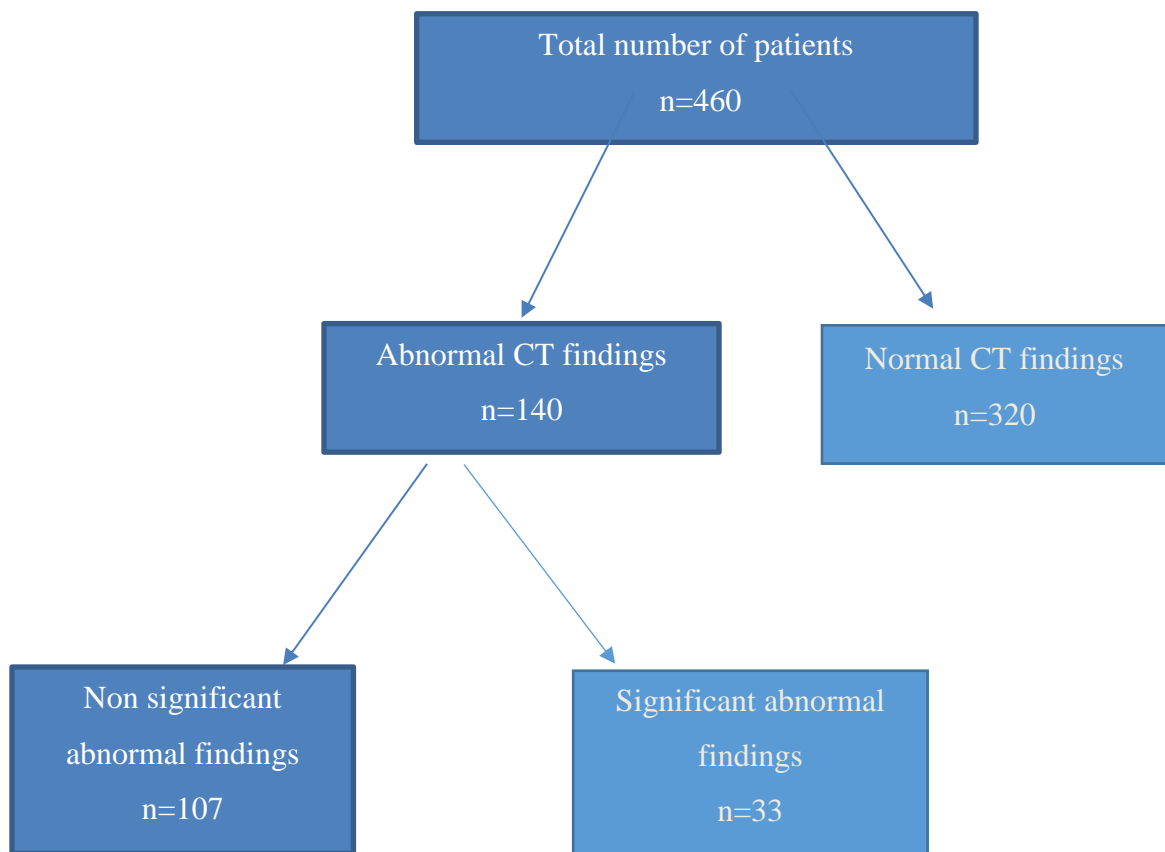


Fig 1. Breakdown of study sample

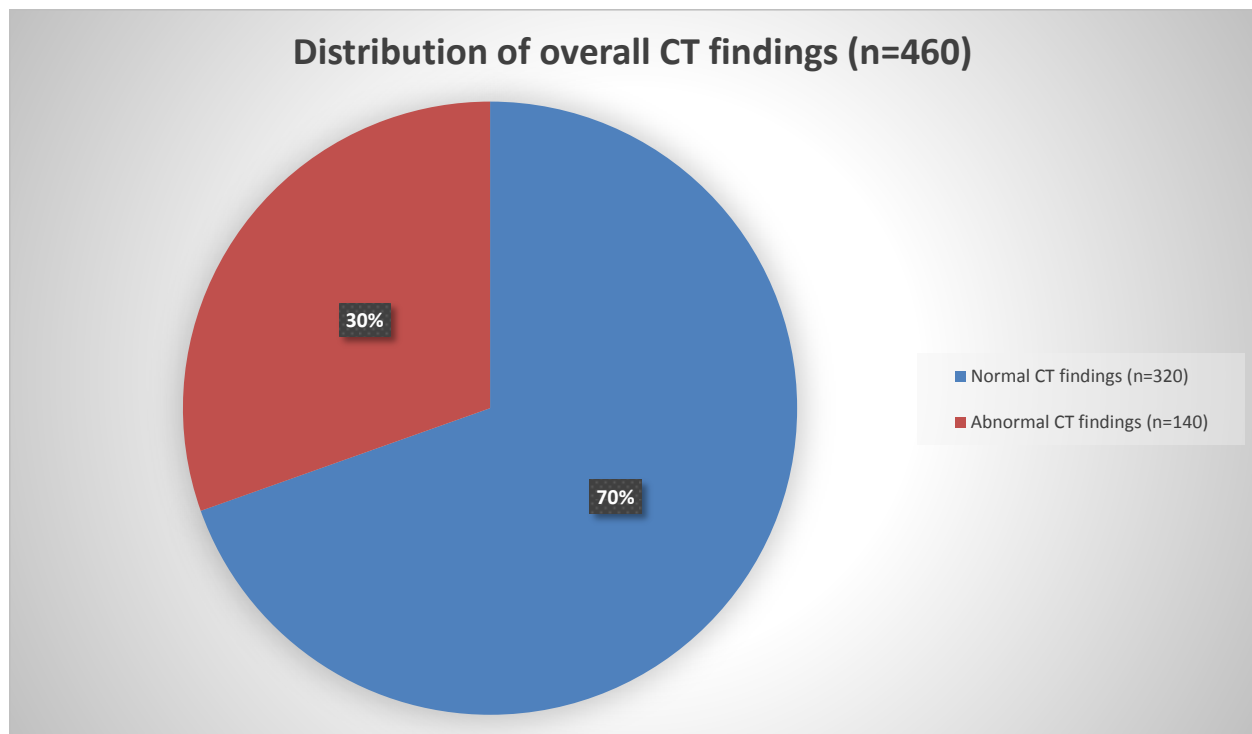


Fig 2. Pie chart demonstrating the distribution of normal and abnormal findings on CT in our sample of patients (n=460).

Of the 140 abnormal CT scan findings, only 7% fulfilled the criteria for significant CT findings and requiring neurosurgical management.

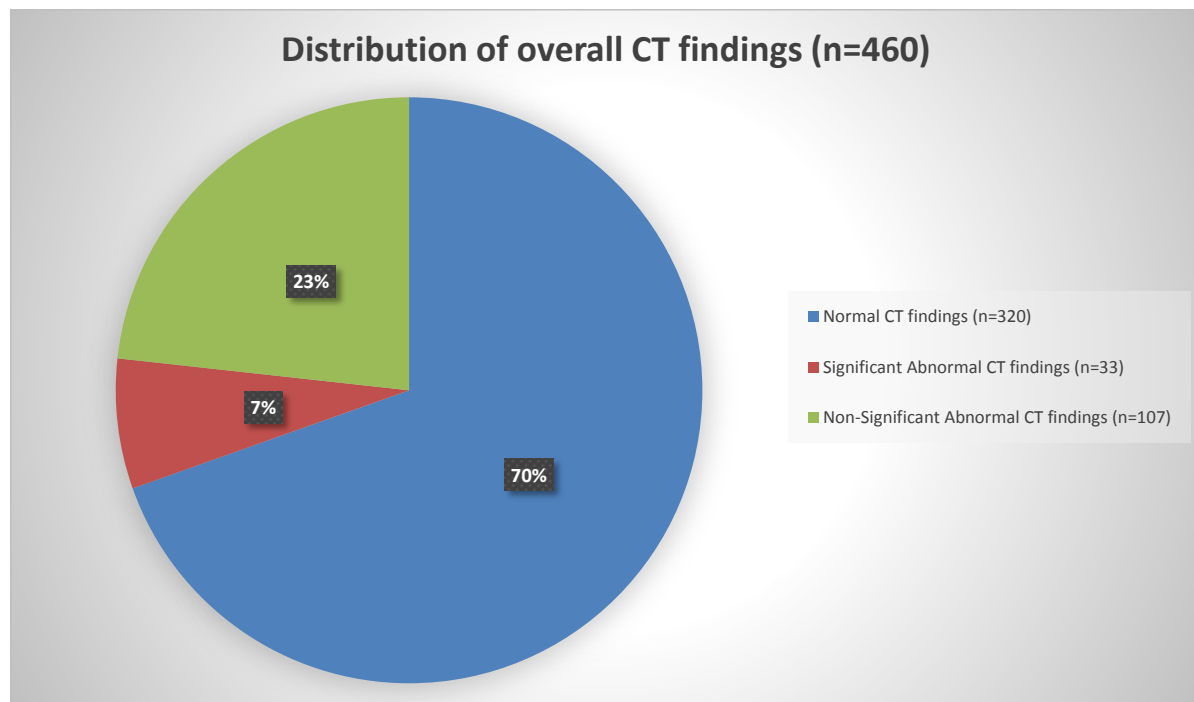


Fig 3. Pie chart further differentiation of the abnormal CT brain in significant and insignificant findings. n=460

5.2 Description of patients presenting with significant CT scan findings.

Of the 33 patients with significant CT abnormality; dizziness, vomiting and headache were found to be the prominent risk factors on presentation. Risk factors included nausea, vomiting, headache and dizziness. No patient in this group was reported as presenting with nausea. (Table 1)

Table 1.

Distribution of clinical findings in patients with significant CT abnormalities (n=33)

| Risk factors | Number of patients |
|--------------------|--------------------|
| No. with dizziness | 7 (21%) |
| No. with nausea | 0 (0%) |
| No. with vomiting | 5 (15%) |
| NO. with headache | 7 (21%) |

Contusion was found to be the most common significant CT abnormality. This was followed by depressed skull fracture and base of skull fracture. Cerebral herniation, extradural hematoma and subdural hematoma were not found in this group of patients (Table 2)

Table 2.

Distribution of significant CT findings in all patients (n=33)

| Significant CT Abnormality | No. of Significant Abnormal finding (n=33) |
|----------------------------|--|
| Contusion | 22 |
| Base of Skull Fracture | 7 |
| Depressed Skull Fracture | 11 |
| Cerebral Herniation | 0 |
| Extradural Collection | 0 |
| Subdural Collection | 0 |
| Cerebral Edema | 0 |

Of the 460 patients in our study, 33 (7%) (95% CI 4.7 – 9.6%) fulfilled our criteria for significant CT findings. Table 3 demonstrates the confidence interval calculation.

| | |
|--|-----------|
| Table 3: | |
| 95% confidence interval for proportion of significant abnormal CT findings | |
| n | 33 |
| N | 460 |
| n/N | 0.0717 |
| $p = (n+2)/(N+4)$ | 0.0754 |
| $var = p*(1-p)$ | 0.0697 |
| $var_a = var/(N+4)$ | 0.0001503 |
| $s = \sqrt{var_a}$ | 1.23% |
| $2*s$ | 2.45% |
| Confidence Interval (p-2s;p+2s) | |
| 4.27% | 9.63% |

6. Discussion

6.1 Implications of the study findings

Our study shows has shown that 7% of 460 patients who had traumatic head injury with loss of consciousness and/or amnesia but with GCS of 15 at presentation, had significant CT findings (95 % confidence interval [CI] 4.72% to 9.63%). Contusion and depressed skull fracture were the most common significant positive findings (66% and 33% respectively). 21 % had base of skull fractures. No patient had subdural or epidural hematoma or cerebral herniation requiring urgent neurosurgical intervention.

These finding is in agreement with a number of previous studies: a large prospective study (1382 patients) conducted by Miller et al who concluded that procedural computed tomography of the brain in patients with a GCS 15 after minor head injury had minimal significance and was not justifiable.²⁴ Stein & Ross et al, in a study designed to examine the same question, concluded that only patients with GCS of less than 15 warrant immediate/urgent CT brain scanning.²⁵ Davis et al after reviewing the CT brains in children with minor head injury with loss of consciousness, found a similar number of CT abnormalities to those found in our study, though they reported a larger number of intracranial hemorrhages (8% vs our 4.7%). Their report did not specify the type of hemorrhage found or whether these patients required neurosurgical intervention but they concluded that CT is a safe and cost effective means of reducing patient admission for overnight observation and that it significantly reduces the cost incurred by missed or delayed head injury management.⁴¹

However, in a prospective study of 712 trauma patients with GCS of 15, Jeret *et al.* (1993) found that 67 patients had intracranial traumatic lesions, 2 of whom required neurosurgical intervention and 1 who died. These authors concluded that there is no risk factor or clinical predictor occurring in isolation or in combination that can provide an accurate prediction of CT abnormality/normality, or that can alter the algorithm of imaging and the management of minor head injury⁴⁰

Hsiang *et al.* (1997) reported a high correlation between headache and minor head injury.¹⁰ Nausea and vomiting are however non-specific symptoms that may, for example, be associated with intoxication and substance abuse rather than as a direct consequence of head injury.³⁴ In our study, patients with significant findings on CT also reported a higher incidence of vomiting (15%) and headache (21%) than those with insignificant or negative CT findings.

Since our study was performed retrospectively and was conducted by reviewing patient reports on a PACS system, details of the actual clinical history and management of these patients with significant abnormality was beyond the scope of our research question. CT head decision rules have been designed in developed countries where the trauma burden, staffing and financial pressures are different to those encountered in South Africa.

In the South African context, the “Kimberly Hospital Rule” proposed by Bezuidenhout and colleagues in 2013 deserves mention. Modified from the well-known National Institute for Health and Care Excellence (NICE) guideline, this offers a single unifying rule that is ideal for a resource limited environment with high prevalence of trauma. Emergency scans are resource intensive. With 90% sensitivity and 45% specificity in the detection of clinically significant intracranial findings, the KHR attempts to justify the timing of emergency CT brains without reducing the number of scans performed. Based on this rule, patients with a normal mental status (GCS 15) but with a history of LOC and/or amnesia are scanned within 8 hours.³⁴ In our geographic region, this would allow the patient to be observed and, if necessary, scanned at the primary treatment centre within the recommended time frame.

The absence of any patient requiring neurosurgical evacuation of intracranial haematoma in our study argues for a role of cautious observation in this patient group. On the basis of our results, we suggest that minor head trauma could be safely managed at primary or secondary level units. In busy tertiary trauma units, the reduction in patient numbers could have a positive impact on the management of those patients with unequivocal head injury. Based on an unpublished study performed in our institution, at present, the time from injury to obtaining an initial scan is an

astounding 18 hours⁴². This is largely attributable to an over-stretched ambulance service which is presently required to transport trauma victims from primary and secondary level facilities for the sole purpose of having a CT scan.

The fiscal argument offered for CT head scanning in MHI to allow rapid triage requires closer examination. Any contusions documented on CT scan, require the patient to be admitted for neurological observations for an undetermined period of time. A follow up CT is often performed to exclude radiological change, even in the absence of neurological deterioration. These prolonged admissions serve to increase financial and staffing burden in these pressurised units.

6.2 Limitations of the current study

Our data was collected retrospectively from the hospital RIS and PACS, relying solely on the summaries written by clinicians on patient request forms. No files or clinical notes were reviewed hence the type of neurosurgical management provided to the patients was not part of the scope of our research. Some variables such as length of loss of consciousness may have been inaccurately estimated. Also, the mode of injury was not always documented. Due to research time constraints, our sample size was smaller than many similar studies. We had a shortfall of 35 patients on our recommended calculated sample size. Small sample size and different patient demographic and socioeconomic factors may play a major role in the different outcomes. Lastly, our study examined the CT scan reports of patients presenting to a single urban tertiary hospital, hence our results may not be representative of the population as a whole.

6.3 Future applications

Currently, at our institution, patients presenting post trauma with normal GCS are imaged urgently in the face of CT resource scarcity. In the light of the findings of this retrospective study, we recommend a large prospective study of patients presenting with head trauma but a GCS of 15. This would be designed to include detailed documentation of mechanism of injury and other associated injuries (including, but not restricted to, suspected cervical spine injuries).

CT head decision rules have proved effective in other countries with reliable sensitivity and specificity. To curb overutilization of this scarce resource, a trial of the Kimberly Head Rule in our institution opens a research opportunity.

7. Conclusion

Our study demonstrated that most CT scans performed in patients who had experienced loss of consciousness after head trauma but who had recovered to normal mental status, (GCS 15 and no focal neurology), were normal. No scans with herniation, sub- or epidural haematoma were identified. However, a small number of patients had significant findings such as intracranial haemorrhage and depressed skull fracture even in the face of normal level of consciousness and normal neurology. A normal level of consciousness (GCS of 15) coupled with absence of neurological deficit, therefore, does not exclude significant traumatic brain injury nor eliminates the role of imaging in this subgroup of patients.

Although only 7% of patients in our study had a significant finding that would warrant tertiary referral, this group of patients cannot be ignored. South Africa is a resource limited country. Many health care centres lack trained personnel and many have no CT scanner. This lack of accessibility may delay imaging and essential surgical management. We therefore agree with the Kimberly Hospital recommendations that patients with minor head injury but a GCS of 15 should be scanned, but that their imaging can safely be delayed by 8 hours. A large well designed prospective study with clearly defined clinical parameters may shed light on the subject. It is likely however that medical litigation and the potentially catastrophic outcome of a missed intracranial injury will continue to drive the demand for CT in the setting of minor head injury.

8. Appendix

8.1 Appendix 1: Ethics clearance



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: shahjeds.arnandien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 February 2015

HREC REF: 098/2015

Dr S Candy
Radiology
Room 30, C7
GSH

Dear Dr Candy

PROJECT TITLE: COMPUTED TOMOGRAPHY FINDINGS IN PATIENTS WITH MINOR HEAD TRAUMA, GLASGOW COMA SCALE 15, A HISTORY OF LOSS OF CONSCIOUSNESS AND AMNESIA (MMeD candidate-Dr Chuma Singata)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 28th February 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Chuma Singata will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312."

*Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

HREC 098/2015

FHS017: Annual Progress Report / Renewal

- 7 FEB 2017

Record Reviews/Audits/Collection of Biological
Specimens/Repositories/Databases/Registries

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

HREC office use only (FWA00001637; IRB00001938)

This serves as notification of annual approval, including any documentation described below.

| | | | |
|--|------------------------|----------------------------------|-----------|
| <input checked="" type="checkbox"/> Approved | Annual progress report | Approved until/next renewal date | 28.2.2018 |
| <input type="checkbox"/> Not approved | See attached comments | | |

| | | | |
|-----------------------------------|---------------|-------------|------------|
| Signature Chairperson of the HREC | Signed | Date Signed | 07/02/2017 |
|-----------------------------------|---------------|-------------|------------|

Principal Investigator to complete the following:

1. Protocol Information

| | | | |
|--|--|---|---|
| Date (when submitting this form) | 06/02/2017 | | |
| HREC REF Number | 098/2015 | Current Ethics Approval was granted until | 27/02/2017 |
| Protocol title | COMPUTED TOMOGRAPHY FINDINGS IN PATIENTS WITH MINOR TRAUMA, GCS 15, history of loss of consciousness | | |
| Principal Investigator | PROF SALLY CANDY | | |
| Department / Office Internal Mail Address | RADIOLOGY DEPARTMENT GROOTE SCHUUR HOSPITAL | | |
| 1.1 Does this protocol receive US Federal funding? | | | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |

2. Protocol status (tick ✓)

| | |
|--|---|
| <input checked="" type="checkbox"/> | Research-related activities are ongoing |
| <input checked="" type="checkbox"/> | Data collection is complete, data analysis only |
| Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository. | |
| Nil | |

3. Protocol summary

| | |
|--|---|
| Total number of records or specimens collected, reviewed or stored since the original approval | 460 |
| Total number of records or specimens collected, reviewed or stored since last progress report | 460 |
| Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report. | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |

4. Signature

| | | | |
|-----------------|---------------|------|---------|
| Signature of PI | Signed | Date | 6/2/17. |
|-----------------|---------------|------|---------|

8.2 Appendix 2

2A. Glasgow Coma Scale¹⁸

Eye opening

Spontaneous = 4

To speech = 3

To painful stimulation = 2

No response = 1

Motor response

Follows commands = 6

Makes localizing movements to pain = 5

Makes withdrawal movements to pain = 4

Flexor (decorticate) posturing to pain = 3

Extensor (decerebrate) posturing to pain = 2

No response = 1

Verbal response

Oriented to person, place, and date = 5

Converses but is disoriented = 4

Says inappropriate words = 3

Says incomprehensible sounds = 2

No response = 1

The severity of TBI according to the GCS score (within 48 h) is as follows:

Severe TBI = 3-8

Moderate TBI = 9-12

Mild TBI = 13-15

2B “CT in Head Injury Patients” CHIP⁷

A CT is indicated in the presence of 1 major criterion

Pedestrian or cyclist versus vehicle

Ejected from vehicle

Vomiting

Posttraumatic amnesia at 4 hours

Clinical signs of skull fracture

GCS score < 15

GCS deterioration < or equal 2 points (1 h after presentation)

Use of anticoagulant therapy

Posttraumatic seizure

Age 60 years

A CT is indicated in the presence of at least 2 minor criteria

Fall from any elevation

Persistent anterograde amnesia

Posttraumatic amnesia of 2 to 4 h

Contusion of the skull

Neurologic deficit

Loss of consciousness

GCS deterioration of 1 point (1 h after presentation)

Age 40–60 years

2C. New Orleans Criteria (NOC)⁴

Computed tomography is required for patients with minor head injury (GCS 15) with any one of the following findings

- Headache
- Vomiting
- Older than 60 years
- Drug or alcohol intoxication
- Persistent anterograde amnesia (deficits in short-term memory)
- Visible trauma above the clavicle
- Seizure

2D. Canadian CT head rule

High risk (for neurosurgical interventions)

- GCS score <15 at two hours after injury
- Suspected open or depressed skull fracture
- Any sign of basal skull fracture (haemotympanum, “panda” eyes, cerebrospinal fluid otorrhoea, battle’s sign)
- Vomiting more than once
- Age \geq 65 years

Medium risk (for brain injury on CT)

- Persistent retrograde amnesia of greater than 30 minutes
- Dangerous mechanism of injury (pedestrian struck by vehicle, ejection from vehicle, fall from greater than three or five stairs)

2E. The Kimberly Head Hospital Rule³⁴

Immediate CTB to be performed within 1 Hour:*

- All patents with GCS <13 on initial or subsequent assessment
- Deterioration of GCS by 2 or more points after initial assessment
- Suspected skull fracture
- Focal neurological deficit
- Patients with GCS 13/14 with 1 of the following
 - Vomiting
 - Seizure
 - Coagulopathy (history of bleeding, clotting disorder, current treatment with warfarin or clopidogrel and aspirin)

Urgent CTB to be performed within 8 hours

- All patients with a GCS<15
- All patients with a GCS 15 with one of the following:
 - Sudden onset of severe headache
 - History of loss of consciousness
 - Continuous vomiting(extracranial causes excluded)
 - Seizure(extracranial causes excluded)

8.3 Appendix 3: Data collection sheet

| Risk Factors | | | | | | | | | | Findings | | | | | | | | | |
|--------------|--------|-----|-----------|-----|-------------|--------|----------|----------|-----------|-------------|-----|-----|----|-----------------|------|------|-----|----|-------|
| | | | | | | | | | | Significant | | | | Non-Significant | | | | | |
| Patient No | GCS 15 | Age | Sex (F/M) | LOC | PTA/Amnesia | Nausea | Vomiting | Headache | Dizziness | DSF | EDC | SDC | CE | CH | BOSF | Cont | LSF | SW | ECCHY |
| 1 | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | | | | | |
| 21 | | | | | | | | | | | | | | | | | | | |
| 22 | | | | | | | | | | | | | | | | | | | |
| 23 | | | | | | | | | | | | | | | | | | | |
| 24 | | | | | | | | | | | | | | | | | | | |
| 25 | | | | | | | | | | | | | | | | | | | |
| 26 | | | | | | | | | | | | | | | | | | | |
| 27 | | | | | | | | | | | | | | | | | | | |
| 28 | | | | | | | | | | | | | | | | | | | |
| 29 | | | | | | | | | | | | | | | | | | | |
| 30 | | | | | | | | | | | | | | | | | | | |
| TOTAL | | | | | | | | | | | | | | | | | | | |

key

DSF

Depressed Skull Fracture

EDC

Extradural Collection

SDC

Subdural Collection

CE

Cerebral Edema

CH

Cerebral Herniation

BOSF

Base Of Skull

Cont

Contusion

LSF

Linear Skull Fracture

SW

Scalp Swelling

ECCHY

Echymosis

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